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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,179

Applicant(s)

HORNE ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30, 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 1-29, 31.

Accordingly, claims 30, 32 are examined in the instant application.

The following are the remaining rejections.

REJECTION UNDER 35 USC 102(e)

Claims 30, 32 remain rejected under 35 USC 102(e), pertaining to being anticipated by US 5,622,852.

Applicant argues that the '852' patent fails to teach the claimed monoclonal antibodies that specifically bind to the human Bad of SEQ ID NO:2, or a fragment thereof consisting of the carboxy terminal 95 amino acid residues of the human Bad polypeptide.

Applicant argues that the 852' patent only describes the generation of polyclonal sera against the mouse Bad polypeptide.

Applicant argues that the difference is only 75%, and this is simply not high enough similarity to ensure that any particular monoclonal antibody generated against mouse Bad would inherently bind to human Bad, given the unpredictable nature of protein structure.

Applicant argues that while it might be possible that a monoclonal antibody against a mouse Bad polypeptide would cross-react with a human Bad polypeptide, the

Examiner fails to provide evidence or substantial reasoning that any antibodies described in the 852' patent would necessarily bind to a human Bad polypeptide.

Applicant's arguments in paper of 05/24/04 have been considered but are found not to be persuasive for the following reasons:

It is noted that US 5,622,852 teaches production of monoclonal and polyclonal antibodies for mouse Bad polypeptide and fragments thereof (column 36, paragraph under Production and application of alpha-Bax antibodies).

US 5,622,852 further teaches that in some applications of these antibodies, where the object is, for example, to identify immunocrossreactive polypeptides that comprise a particular structural moiety, such as a bcl-2 binding domain, it is preferable that a fragment of Bad, such as BH1 or BH2 domain, rather than the entire native protein, is used as an antigen for making antiserum or monoclonal antibodies (column 37, lines 45-60).

Since there is no specific epitope of the monoclonal antibody that binds to SEQ ID NO:2 is recited in the claim 30, i.e. there is no particular monoclonal antibody that is bound to SEQ ID NO:2 recited in the claim, monoclonal antibodies to mouse Bad polypeptide seem to be the same as the claimed monoclonal antibody that binds to human Bad polypeptide, because one would expect that there numerous shared epitopes of various monoclonal antibodies to the mouse Bad with the claimed monoclonal antibodies to the full length sequence SEQ ID NO:2 of 168 amino acids, in view of MPSRCH search report (of record), which shows 75% homology throughout the entire length of the sequence.

Although the reference does not specifically teach that the monoclonal antibody would bind to SEQ ID NO:2, however, the claimed monoclonal antibody appears to be the same as the prior art monoclonal antibody. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Further, since the BH1 region of mouse BAD (amino acids 137-160) is within the corresponding 95 amino acids at the carboxyl end of SEQ ID NO:2 of the claimed invention (amino acids 74-168 of SEQ ID NO:2) (see MPSRCH search report, of record), and since there is extensive homology between the BH1 region of the mouse Bad (amino acids 137-160) and corresponding region of the claimed SEQ ID NO:2, i.e. from a total of 24 amino acids of the BH1 region, there is only a difference of two amino acids, amino acids 159-160, at the end of BH1 region, one would expect that a monoclonal antibody to the BH1 region of mouse Bad would also bind to human Bad polypeptide consisting of 95 contiguous amino acids at the carboxy end of SEQ ID NO:2.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Application/Control Number: 10/066,179
Art Unit: 1642

Page 6

MINH TAM DAVIS

August 02, 2004